



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/509,368

09/28/2004

Joachim Bunger

MERCK-2926

3834

23599

7590

08/06/2008

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

HUGHES, ALICIA R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,368	Applicant(s) BUNGER ET AL.	
	Examiner ALICIA R. HUGHES	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4-15 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 3 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-20 are pending. However, only claims 3 and 16 are the subject of this Office Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Restriction Requirement

Applicant's election with traverse of Group I, which includes claims 1-17 and 20 and within Group I, further electing a method for the prophylaxis and protection of human skin against wrinkling and electing (S)-1,4,5,6-tetrahydro-2-methyl-4-pyrimidinecarboxylic acid as a species of the compound of formula Ia or Ib, in the reply filed on 27 March 2008 is acknowledged.

Claims 1-2, 4-15, and 17-20 are withdrawn from consideration, being drawn to a non-elected invention, there being no allowable generic or linking claim. See 37 C.F.R. 1.142(b). Applicant timely traversed the restriction (election) requirement in the reply filed on 27 March 2008, stating that the PTO has not established that it would pose an undue burden to examine the full scope of the application.

As noted prior, the groups of inventions are not so linked as to form a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features and as a result, pursuant to 37 CFR 1.499, the applicant is required to elect a single invention. The requirement is deemed FINAL.

Claim Rejection - 35 U.S.C. §112, First Paragraph

Claims 3 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 3 and 16 are drawn to “administering to a subject in need thereof a compatible solute.” However, the specification is written broadly, simply advising that “... compatible solutes are ... osmotically active substances [that] prevent liquid outflow into the medium (drying out) and owe their name to the fact that they do not impair cell metabolism, even in high cytoplasmic concentration [sic] (up to about 2 molal), i.e. are compatible with metabolism” (Specification, p. 1, line 31 through p. 2, line 4). The listing of this non-exacting reference is insufficient to meet the written description provision of 35 U.S.C. 112, first paragraph.

In short, the specification is lacking sufficient written description to support the genus disclosed in claims 3 and 16, because compatible, effective, solutes are not clearly defined in the specification and the conditions associated therewith are not sufficiently and completely disclosed so as to inform one skilled in the art how to practice the presently claimed invention.

As a matter of law, an adequate written description requires more than a mere statement that the matter claimed is part of the invention accompanied by reference to potential compounds. Disclosure of the compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Claim Rejection – 35 U.S.C. §102

Claims 3 and 16 are rejected under 35 U.S.C. §102(b) as being anticipated clearly by U.S. Patent No. 6,130,254 [hereinafter referred to as “Fisher et al”].

For the purpose of examination herein, the pending claims are given their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted “in view of the specification” without importing limitations from the specification into the claims unnecessarily). *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969).

In assigning such broad interpretation in the absence of a clear definition of compatible solute in the specification, the Office defines compatible solute to include retinoids.

Fisher et al. defines photoaging as changes in appearance and/or function of human skin as a result of repeated exposure to sunlight, and most especially regarding wrinkles (Col. 1, lines 19-22). One invention in Fisher et al is directed "to inhibiting (i.e., reducing or preventing) photoaging of skin, especially human skin (Col. 4, lines 61-63) and yet another contemplates a composition for topical administration prior to ultraviolet exposure that contains a retinoid as a prophylactic against photoaging (Col. 6, lines 7-12; Col. 22, lines 11-22, claim 31). In view of the foregoing, claims 3 and 16 are clearly anticipated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 A.M. until 5:00 P.M. on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application is proceeding is assigned 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614